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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/706,886	11/06/2003	Michiel Onne Elema	05432/100K425-US1	9219

7590 06/16/2005

DARBY & DARBY P.C.  
805 THIRD AVENUE  
NEW YORK, NY 10022

EXAMINER
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HOWARD, SHARON LEE

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 06/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/706,886

Applicant(s)

ELEMA ET AL.

Examiner

Sharon L. Howard

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED. (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 22 March 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-13, 15 and 17-19 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 20 is/are allowed.
- 6) ☒ Claim(s) 1-13, 15 and 17-19 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

Receipt of the Amendment, the remarks and the three months extension of time filed on 3/22/05 have been acknowledged by the examiner.

Claims 1-13,15,17-20 remain pending.

***Claim Rejections - 35 USC § 103***

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-13,15,17-19 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Koch et al. (USP 5,912,256).

Koch teaches pharmaceutical compositions known in the art for treating diseases which are caused by disorders of the serotonin-affected neurological systems (see col.1, lines 8-14). Koch discloses compositions such as tablets, chewable tablets and capsules are known to be used. Koch teaches that tablets are prepared by wet or dry granulation and usually contain diluents and binders such as, for example lactose, starch, sugar, sodium chloride, natural and synthetic gums such as acacia, alginates.

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Koch also teaches that disintegrators, polyethylene glycol which defines a binder and a polymer consisting of ethylcellulose (see col.23, lines 51-67 and col.24, lines 8-32) are formulated into the tablets. Koch teaches Citalopram (see col.21, lines 15 and 16). Absent a showing in the criticality of the particular drug, there are no unexpected results since the prior art teaches Citalopram which is a homologue of Escitalopram.

Koch does not teach the amount of the hydrophilic cellulose ether polymer nor the amount of the hydrophilic melt binder.

However, one of ordinary skill in the art would be able to determine the particular amounts through routine experimentation. It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the Koch reference because Koch teaches a wet granulated composition comprising a polymer, a binder and a drug. The expected result would be a pharmaceutical composition which is compressed into tablets.

**Claim 20 is allowable.**

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

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Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-13,15,17-20 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-23 of U.S. Patent No. 5,403,593. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the instant application are directed to a melt granulated substantially homogeneous composition comprising (A) one or more hydrophilic cellulose ether polymer; (B) a hydrophilic melt binder; and (C) a therapeutically active medicament which forms a genus, whereas the patented claims are directed to a composition for preparing a therapeutically active sustained release dosage form which comprises a melt granulated substantially homogeneous composition comprising (A) one or more hydrophilic cellulose ether polymer; (B) a granulating medium comprising polyethylene glycol and a glyceryl ester of at least one C12-28 fatty acid; and (C) a therapeutically active medicament which forms a species. The claims are similar in scope, however, Claim 1 in the instant application differs from claim 1 in the patent in that the instant claimed glyceryl ester species is an obvious variant of the genus claimed and therefore it would have been obvious for one of ordinary skill in the art at the time of the instant invention to use glyceryl ester in the genus claim having the reasonable expectation of obtaining a stable dosage formulation which is solid-shaped.

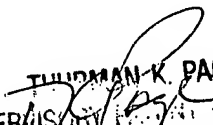
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon L. Howard whose telephone number is (571) 272-0596. The examiner can normally be reached on 9:00am - 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Sharon Howard  
June 6, 2005



THURMAN K. PAGE  
SUPERVISORY EXAMINER  
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